

IN THE CLAIMS:

A listing of the claims is as follows:

1. (Original) An apparatus for determining the orientation of a medical device within a patient's body, comprising:

a catheter having a tube wall defining a lumen therethrough; and

a plurality of tube wall bending indicators located at least on or within the catheter wall at a reference portion of the catheter to become curved where the catheter passes through an anatomical reference when the distal end of the catheter is at a target site within the patient's body;

wherein the plurality of tube wall bending indicators provide an indication of tube wall bending to indicate the orientation of the reference portion of the catheter relative to the anatomical reference.

2. (Original) The apparatus of claim 1, wherein the catheter further comprises:

a distal outlet in communication with the lumen, and the orientation of the catheter distal outlet relative to the anatomical reference is to be determined based on a predetermined orientation of the catheter distal outlet relative to the reference portion of the catheter and the orientation of the reference portion of the catheter relative to the anatomical reference.

3. (Currently amended) The apparatus of claim 1 wherein the tube wall bending indicators comprise:

a plurality of strain gauges for providing said indication of tube wall bending by changing an electrical resistance in accordance with an amount of tube wall bending within the vicinity of each strain gauge.

4. (Currently amended) The apparatus of claim 3, further comprising an orientation display to display an indication of the orientation of the reference portion of the catheter relative to the anatomical reference based on the electrical resistance change of the strain gauges.

5. (Original) The apparatus of claim 1, wherein the tube wall bending indicators comprise:

a plurality of rods movably embedded in the catheter wall, wherein each of the rods extends from a proximal end of the catheter to at least the reference portion of the catheter that becomes curved when the catheter is placed at the target site, the rods to provide said indication of tube wall bending by changing an amount of protrusion relative to the proximal end of the catheter in accordance with an amount of tube wall bending in the vicinity of each rod.

6. (Withdrawn) A method of using a catheter comprising:

placing a distal end of a catheter at a target site within a patient's body; and

determining the orientation of the distal end of the catheter relative to the target site based on an indication from tube wall bending indicators of localized tube wall bending around a known anatomical reference.

7. (Withdrawn) The method of claim 6 wherein said determining the orientation of the distal end of the catheter relative to the target site comprises:

determining the orientation of the catheter relative to the target site based on a change in tensile stress in the tube wall bending indicators.

8. (Withdrawn) The method of claim 6 wherein said determining the orientation of the distal end of the catheter relative to the target site comprises:

determining the orientation of the catheter relative to the target site based on a change in compressive stress in the tube wall bending indicators.

9. (Withdrawn) The method of claim 6 wherein said determining the orientation of the distal end of the catheter relative to the target site comprises:

determining the orientation of the catheter relative to the target site based on a change in tensile stress and compressive stress in the tube wall bending indicators.

10. (Withdrawn) The method of claim 6 wherein said determining the orientation of the distal end of the catheter relative to the target site comprises:

determining the orientation of the catheter relative to the target site based on a change in tensile strain in the tube wall bending indicators.

11. (Withdrawn) The method of claim 6 wherein said determining the orientation of the distal end of the catheter relative to the target site comprises:

determining the orientation of the catheter relative to the target site based on a change in compressive strain in the tube wall bending indicators.

12. (Withdrawn) The method of claim 6 wherein said determining the orientation of the distal end of the catheter relative to the target site comprises:

determining the orientation of the catheter relative to the target site based on a change in tensile strain and compressive strain in the tube wall bending indicators.

13. (Withdrawn) A system for determining the orientation of a medical device within a patient's body, comprising:

a catheter having a tube wall defining a lumen therethrough and a distal outlet proximate to a distal end of the catheter in communication with the lumen;

a plurality of tube wall bending indicators located at least on or within the tube wall at a reference portion of the catheter to become curved where the catheter passes through an anatomical reference when the distal end of the catheter is proximate to a target site within the patient's body, the plurality of tube wall bending indicators to provide an indication of the orientation of the reference portion of the catheter relative to the anatomical reference; and

an imaging device to image the catheter distal end, the imaging device to provide an indication of a position of the catheter distal end relative to the target site;

said orientation of the distal outlet relative to the target site to be determined based on the indicated orientation of the reference portion of the catheter relative to the anatomical reference as indicated by the tube wall bending indicators and the position of the catheter distal end as indicated by the imaging device.

14. (Withdrawn) The system of claim 13, wherein the imaging device comprises a fluoroscopic device.

15. (Withdrawn) The system of claim 13, wherein the tube wall bending indicators comprise:

a plurality of strain gages to provide said indication of tube wall bending by changing an electrical resistance in accordance with an amount of tube wall bending within the vicinity of each strain gage.

16. (Withdrawn) The system of claim 15, further comprising:

an orientation display to display an indication of the orientation of the reference portion of the catheter relative to the anatomical reference based on the electrical resistance change of the strain gages.

17. (Withdrawn) The system of claim 13, wherein the tube wall bending indicators comprise:

a plurality of rods movably embedded in the catheter wall, wherein each of the rods extends from a proximal end of the catheter to at least the reference portion of the catheter that becomes curved when the catheter is placed at the target site, the plurality of rods to provide said indication of tube wall bending by changing an amount of protrusion relative to the proximal end of the catheter in accordance with an amount of tube wall bending in the vicinity of each rod.

18. (Withdrawn) A method for determining the orientation of a medical device within a patient's body, comprising:

placing a distal end of a catheter at a target site within the patient's body, the catheter including a tube wall defining a lumen therethrough, a distal outlet in communication with the lumen, and a plurality of tube wall bending indicators located at least on or within the tube wall at a reference portion of the catheter to become curved where the catheter passes through an anatomical reference when the distal end of the catheter is at the target site;

determining the orientation of the reference portion of the catheter relative to the anatomical reference based on an indication of tube wall bending provided by the plurality of tube wall bending indicators;

determining the position of the catheter distal end relative to the target site by imaging of the distal end of the catheter with an imaging device; and

determining the orientation of the catheter outlet relative to the target site based on the orientation of the reference portion of the catheter relative to the anatomical reference as indicated by the tube wall bending indicators and the position of the catheter distal end as indicated by the imaging device.

19. (Withdrawn) The method of claim 18, wherein determining the orientation of the reference portion of the catheter relative to the anatomical reference further comprises:

identifying one of the plurality of bending indicators indicating the highest tensile stress or strain in the catheter wall as the bending indicator closest to an outside radius of the catheter in the curved portion of the catheter within the anatomical reference; and

determining the orientation of the reference portion of the catheter relative to the anatomical reference based on the orientation of the bending indicator corresponding to the highest tensile stress or strain in the tube wall.

20. (Withdrawn) The method of claim 18, wherein the tube wall bending indicators comprise:

strain gages for providing said indication of tube wall bending by changing an electrical resistance in accordance with an amount of tube wall bending within the vicinity of each strain gage.

21. (Withdrawn) The method of claim 18, wherein the tube wall bending indicators comprise:

a plurality of rods movably embedded in the catheter wall, wherein each of the rods extends from a proximal end of the catheter to at least the reference portion of the catheter that becomes curved when the catheter is placed at the target site, the rods for providing said indication of tube wall bending by changing an amount of protrusion relative to the proximal end of the catheter in accordance with an amount of tube wall bending in the vicinity of each rod.

22. (New) The apparatus of claim 4, further comprising signal wires linking each of the plurality of strain gauges to the orientation display, and wherein the electrical resistance changes in the strain gauges are transmitted to the orientation display via the signal wires.

23. (New) The apparatus of claim 3, wherein the strain gauges are located within the catheter wall.

24. (New) The apparatus of claim 1, wherein bending of the tube wall imparts tensile or compressive stress on one or more of the bending indicators.

25. (New) The apparatus of claim 1, wherein the bending indicators comprise:

a plurality of rods longitudinally disposed within the tube wall, wherein each of the rods are free to move longitudinally relative to the tube wall, and wherein each of the rods extends from a proximal end of the catheter to at least the reference portion of the catheter.

26. (New) The apparatus of claim 25, wherein the distal ends of the rods are fixed to the tube wall.

27. (New) The apparatus of claim 25, wherein each of the rods protrudes from the proximal end of the catheter, and wherein the amount of protrusion of each rod varies according to the amount of tube wall bending in the vicinity of each rod.

28. (New) The apparatus of claim 25, further comprising a panel at a proximal portion of the catheter, wherein the proximal ends of the rods emerge from the face of the panel.

29. (New) The apparatus of claim 28, wherein the panel is located on the proximal end of the catheter.

30. (New) The apparatus of claim 28, further comprising a side tube connected to a proximal portion of the catheter, wherein the rods are routed through the side tube, and wherein the panel is located on the side tube.

31. (New) The apparatus of claim 28, wherein all the rods extend from the face of the panel approximately the same distance when the catheter is in an unbended configuration.

32. (New) The apparatus of claim 1, wherein the catheter is radiopaque under x-ray fluoroscopy.